



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/372,474	08/11/1999	ELDON E. BAIRD	238/168	1434

7590 02/03/2003

Richard J. Warburg, Esq.
FOLEY & LARDNER
P.O. Box 80278
San Diego, CA 92138-0278

EXAMINER

MARSCHEL, ARDIN H

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/372,474

Applicant(s)
Baird et al.

Examiner
Ardin Marschel

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 3, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 38, and 42-49 is/are pending in the application.
~~Claim(s) 6-37 and 39-41 have been canceled.~~ ~~Claims withdrawn from consideration~~
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 38, and 42-49 is/are rejected.
- 7) ☒ Claim(s) 2 and 5 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Applicants' arguments, filed 10/3/02, have been fully considered and they are deemed to be persuasive to overcome the rejections set forth in the Office Action, mailed 6/10/02. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Upon reconsideration, however, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The presently pending claims are directed only to polyamide design and synthesis methods, polyamides, and diagnostic kits whereas, in contrast, the present title is directed to design, synthesis, and use of polyamides. No use is claimed and the present title lacks polyamide compositions and kits.

Claims 3, 4, and 38 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 4 appear to conflict regarding what is meant by binding affinity. In claim 3 the binding affinity seems to be defined as being below nanomolar whereas confusingly in claim 4 the binding affinity seems to be higher via a ten-fold criteria.

One citation is interpreted as in claim 3 that the binding affinity is unlimited as to a lower number whereas claim 4 indicates that it is above a certain number. It is acknowledged that binding affinity in the art may be measured as a dissociation constant thus making it reasonable that a lower number as in claim 3 is such a dissociation constant. If, however, a dissociation constant is utilized then a presumed tighter binding affinity in claim 4 should be for target DNA sequences and be a lower rather than a higher value. This conflicts with what is indicated in claim 4. Thus, it is confusing as to whether claim 3 is directed to a dissociation constant whereas claim 4 is directed to an association constant, both being claimed as a binding affinity. Clarification via clearer claim wording is requested as to whether claims 3 and 4 are evaluating binding affinity via a dissociation constant or a association constant.

Claim 38 is vague and indefinite due to a lack of antecedent basis for "binding pair" therein being cited as β/β therein but without antecedent basis for such a pair in either of claims 2 or 1 from which claim 38 depends directly or indirectly.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1 and 42-45 are rejected under 35 U.S.C. § 101 because they are directed to non-statutory subject matter.

As summarized in the MPEP in section 2106, part IV, B, 1, the arrangement of data is nonstatutory subject matter. Instant claims 1 and 42-45 are directed to design of a polyamide which is an arrangement of data regarding monomers therein to result in the design of a polyamide. No physical process or steps are noted in said claims 1 or claims 42-45. Thus, these claims are directed to nonstatutory subject matter. It is noted, in contrast, that claim 2 at least synthesizes a polyamide.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38 and 46-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,506,906;

recently issued. Although the conflicting claims are not identical, they are not patentably distinct from each other because the respective sets of claims contain common embodiments of polyamides. The polyamides as designed by the method of instant claim 1 contain a γ -aminobutyric acid residue as well as heterocyclic ring residues as described in claim 1 and depicted specifically in claim 49. One embodiment, for example, in claim 1 of said recently issued Patent is directed to parameter n at least being 6 wherein the "Y" moiety is selected as the righthand structure in said claim 1 wherein parameter p therein is 2 thus resulting in this moiety containing the γ -aminobutyric acid residue with a rightmost NH moiety as also seen in the NH moiety in instant claim 49 just to the right of the γ -aminobutyric acid residue. In claim 1 of said Patent the Y moiety is independently selected and therefore can be of the γ -aminobutyric acid residue type for one selection with the remainder being the simpler NH linkage thus resulting in the polyamide of instant claim 49. In claim 1 of the Patent the moiety "Z" may be selected as parameter $r = 1$ thus making it β -alanine which is also contained within the instant R_1 moiety as in instant claims 1 or 49. The remainder of the righthand tail of the structure of polyamide of claim 1 of the Patent is that of the remainder of the instant R_1 moiety as in instant claims 1 or 49. The other R groups of the respective structures also contain common residues thus resulting in common

polyamides being claimed between the respective claim sets.

Claims 2 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CAR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arden Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 3, 2003

Arden H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER